

## REMARKS

### **1. The Claims**

Claims 1 – 11 were previously canceled. Claims 12-25 were pending in this application. Claims 16-22 have been withdrawn. Claims 12-15 and 23-25 stand rejected in this application.

In the claims listing above, claims 12-15 and 24-25 are amended, and claims 26 and 27 are newly added. Therefore, upon entry of the amendments to the claims, claims 12-15 and 23-27 will be pending.

New dependent claims 26 and 27 recite methods of treatment of neuralgia pain or neuropathic pain that are accompanied by an increase in muscle tone. Support for these claims can be found in the originally filed claims and in the specification in Paragraph [0012].

### **2. The Amendments to the Specification**

The title has been amended to replace “Pains” with its singular form “Pain.”

The specification has been amended in two places to correct the tense from past tense to present tense. The tense in these two instances was copied, and inadvertently not corrected, during the preparation of this application from the related application 10/727,658 also filed on 12/05/2003, which is also pending before the Examiner.

### **3. Claim rejections under 35 USC 112**

Claims 12-15 and 23-25 are rejected under 35 USC §112, second paragraph, as being indefinite. Examiner contends that the recitation “neuralgia pain, also known as neuropathic pain” in claims 12 and 15 recites a broad limitation followed by a narrower range/limitation. Claims 12 and 15 are amended from “neuralgia pain, also known as neuropathic pain” to “neuralgia pain or neuropathic pain” as suggested by the Examiner to obviate this rejection.

Claims 14-15 are also rejected under 35 USC §112, second paragraph. Examiner contends that the limitation “other tolperisone analogs” is indefinite because it is not clear what the term refers to. Applicants respectfully traverse because it is readily apparent to one of skill in the art what the term “tolperisone analogs” refers to. *See, e.g.*, U.S. 4,181,803 “Propiophenone Derivatives in the Treatment of Pathological Muscular Conditions” to Morita et al.; U.S. 4,528,299 “1-(2,3-Dimethyl-4-Methoxyphenyl)-2-Methyl-3-(1-Pyrrolidiny)-1-Propanone and Anti-spastic use thereof” to Uno et al.

Claims 12 and 23-25 are rejected under 35 USC §112, second paragraph as allegedly failing to enable a person skilled in the relevant art to practice the invention commensurate in scope with those claims. The Examiner has acknowledged that the specification is enabling for specific sodium channel inhibitors, but the Examiner asserts that the specification is not enabling for “sodium channel inhibiting or-influencing substance[s].” Applicants have narrowed the claims by amending the claims to recite “sodium channel inhibiting substance” in place of “sodium channel inhibiting or-influencing substance.” Sodium channel inhibitors constitute a class of materials that is well known in the art. *See, e.g.*, Cai et al. (U.S. 6,281,211) (particularly “Related Background Art” in column 1, 18-56). In addition, the Examiner has acknowledged “the specification describes tolperisone, eperisone, silperisone, riluzole, propafenone, lidocaine, flecainide, and metixen as suitable” sodium channel inhibitors. Office Action at page 4, lines 7-9. Thus the specification provides eight examples of structurally diverse sodium channel inhibitors. In view of the narrower breadth of the amended claims and the specification’s disclosure of eight structurally diverse sodium channel inhibitors, Applicants respectfully submit that the amended claims are allowable.

#### **4. Claim rejections under 35 USC 103(a)**

Claims 12-15 and 23-25 stand rejected under 35 USC §103(a) in view of Rundfelt et al. (US 6,117,900) over Cai et al. (US 6,281,211). In order to establish a *prima facie* case of obviousness there must be some suggestion or motivation in the prior art to combine reference teachings. MPEP §2143. Because neither reference expressly suggests the combination use of retigabine with a sodium channel blocker for the treatment of neuropathic pain, it appears that the Examiner is relying on a combination of equivalents known for the same purpose to establish a *prima facie* case of obviousness. MPEP §2144.06. However, the specification discloses the combination use of sodium channel blockers with a potassium channel opener, such as retigabine, to treat neuropathic pain while also decreasing muscle tone. Potassium channel openers and sodium channel blockers are each distinct art recognized classes of materials, and are not considered equivalents in the relevant art.

Not only is there no suggestion in the prior art for a combination of references, but Cai teaches away from a combination. Discussing the uses of sodium channel inhibitors, Cai writes that “[i]n addition to the above-mentioned clinical uses [three of the previously mentioned sodium channel blockers] are *occasionally* used to treat neuropathic pain.” Column 1, lines 49-54 (emphasis added). Cai implies that it is unusual to use sodium channel blockers to treat

neuropathic pain; and hence one of skill in the art would not be motivated to combine the use of sodium channel blockers with another class of compounds to treat neuropathic pain in particular. Consequently, Applicants respectfully submit that a *prima facie* case of obviousness has not been established and therefore a rejection of the claims on this basis would be improper.

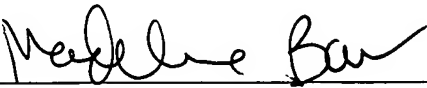
Claims 14 and 15 also stand rejected under 35 USC §103(a) in view of Rundfelt over Cai, and further in view of the applicants admitted prior art of record in the specification. For the same reasons discussed above regarding the absence of a suggestion of motivation to combine Rundfelt with Cai, Applicants respectfully submit that a *prima facie* case of obviousness has not been established and therefore a rejection of the claims on this basis would be improper.

#### CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the claim rejections and respectfully submit that this application is now in condition for allowance, which action is earnestly solicited. If any issues remain that could be addressed by a telephone conversation, the Examiner is cordially invited to contact Applicants' undersigned attorney at the number shown below.

Respectfully submitted,

Dated: \_\_\_\_\_



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